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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,134

12/18/2006

Pablo Steinberg

101215-219

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27387

7590

03/23/2010

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EXAMINER

STAPLES, MARK

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,134	<b>Applicant(s)</b> STEINBERG ET AL.	
	<b>Examiner</b> MARK STAPLES	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03/01/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/01/2010 has been entered.

2. Applicant's amendment of claims 1 and 9 in the paper filed on 03/01/2010 is acknowledged.

Claims 1-6, 9, and 11-14 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Rejections that are Withdrawn**

#### ***Claim Rejections Withdrawn - 35 USC § 112 First Paragraph***

3. The rejection of claims 1-6, 9, and 11-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant's amendments to claims 1 and 9 have overcome this rejection.

### **Rejections that are Maintained**

***Claim Rejections Maintained - 35 USC § 103***

4. The rejection of claims 1, 4-6, 9, 11, and 14 under 35 U.S.C. 103(a) as being unpatentable over Salahshor et al. (1999, previously cited), Davies et al. (June 2002, previously cited), Kmiec et al. (WO200173002 published 2001, previously cited), Shuber et al. (WO200118252 published 2001, previously cited), Ferrie et al. (GB2327497 published 1999, previously cited), Coste et al. (1998, previously cited), Nollet et al. (1996, previously cited), Albertsen et al. (United States Patent 6,114,124 issued 2000, previously cited), Ikawa et al. (1988, previously cited), McCormick (1999), Buck et al. (1999, previously cited), and Stratagene (1988) is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the cited prior art does not suggest that: "the specific molecular modifications necessary to achieve the claimed invention" (citing *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995) and further that there was no motivation: "to try to obtain a gene that was yet undefined and may have constituted many forms." However as given in the previous rejection, the genes recited in the instant claim were known and the nucleic acid sequences containing the sequences of the specifically claimed primers were also known (see Table 1 of Office action mailed on 05/26/2009). The prior of Buck et al., as already given, teaches that primer sequences can be made from any known sequence. Buck et al. thus teach "the specific molecular modifications necessary to achieve the claimed invention" from known genes. And as was pointed out in the prior Office Action, Buck et al. extensively investigated nucleic acid amplification, and all of the permutations pointed to the acceptably of use of a multitude of primer pairs along a

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targeted sequence for amplification. This is a strong motivation to vary primers in a given amplification method, the instant methods included. Furthermore, the use of the recited gene combination was also taught by the prior art of McCormick.

Applicant also points to the instant specification for support that the claimed invention was an improvement and has amended claims 1 and 9 to recite this improved methods and kits in claim 1 and 9 preambles, respectively. However, neither Applicant nor the instant specification provides evidence that this improvement was outside routine optimization and was unexpected in view of the cited prior art.

5. The rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Salahshor et al., Davies et al., Kmiec et al., Shuber et al. (2001), Ferrie et al., Coste et al., Nollet et al., Albertsen et al., Ikawa et al., McCormick, Buck et al., and Stratagene as applied to claim 1 above, and further in view of Gerry et al. (1999) is maintained.

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that as the rejection of claim 1 should be withdrawn that this rejection should also be withdrawn. However, as the rejection of claim 1 is maintained, this rejection is also maintained.

6. The rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Salahshor et al., Davies et al., Kmiec et al., Shuber et al. (2001), Ferrie et al., Coste et al., Nollet et al., Albertsen et al., Ikawa et al., McCormick, Buck et al., and Stratagene as applied to claim 1 above, and further in view of Shuber et al. (WO199858081

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published 1998) is maintained. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that as the rejection of claim 1 should be withdrawn that this rejection should also be withdrawn. However, as the rejection of claim 1 is maintained, this rejection is also maintained.

7. The rejection of claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Salahshor et al., Davies et al., Kmiec et al., Shuber et al. (2001), Ferrie et al., Coste et al., Nollet et al., Albertsen et al., Ikawa et al., McCormick, Buck et al., and Stratagene as applied to claim 1 above, and further in view of Baba et al. (1996) is maintained. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that as the rejection of claim 1 should be withdrawn that this rejection should also be withdrawn. However, as the rejection of claim 1 is maintained, this rejection is also maintained.

### **Conclusion**

8. No claim is free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/  
Primary Examiner, Art Unit 1637  
March 19, 2010